UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

09/368,670

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
			VB

03703 HM22/0131
BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD
P O BOX 368
RIDGEFIELD CT 06877

EXAMINER	
LUKTON	

ART UNIT	PAPER NUMBER
1631	11

DATE MAILED: 01/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No	Applicant(s)
09/368,670	Llinas-Brunet
Examiner	**Group Art Unit**
David Lukton	1653

X Responsive to communication(s) filed on *Nov 24, 2000*

This action is **FINAL.**

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133) Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

X Claim(s) *1-28, 30-35, 37-92, and 96-102* is/are pending in the applicat

Of the above, claim(s) *67-72, 75, 78, 81, 83, 84, 89-92, and 97-99* is/are withdrawn from consideration

Claim(s) _____ is/are allowed.

X Claim(s) *1-28, 30-35, 37-66, 73, 74, 76, 77, 79, 80, 82, 85-88, 96, and 100-102* is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d)

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e)

Attachment(s)

Notice of References Cited, PTO-892

X Information Disclosure Statement(s), PTO-1449, Paper No(s) 6

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Pursuant to the directives of paper No. 10 (filed 11/24/00), claims 1, 23, 32, 40, 45, 54, 58-61 63, 67, 96 have been amended. Claims 1-28, 30-35, 37-92, 96-102 are pending. Claims 1-28, 30-35, 37-66, 73, 74, 76, 77, 79, 80, 82, 85-88, 96, 100-102 are examined in this Office action; claims 67-72, 75, 78, 81, 83, 84, 89-92 and 97-99 are withdrawn from consideration.

Applicants' arguments filed 11/24/00 have been considered and found not persuasive with respect to the §112-first paragraph rejection.

*

This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with regard to the sequence disclosures.

See, for example, the sequence on page 4, line 21.

Applicant is given the time period set in this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-28, 30-35, 37-66, 73, 74, 76, 77, 79, 80, 82, 85-88, 96, 100-102 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1, and several other claims, recite the term "pharmaceutically acceptable". This implies an assertion of therapeutic efficacy. Applicants have shown that several of the claimed compounds are effective to inhibit HCV protease *in vitro*, however, it remains to be determined whether in fact this inhibition will occur in vivo, and if it does, whether it will lead to a perceptible improvement in the condition of a patient afflicted with such an infection. Extrapolation from the test tube to the intact mammal is a precarious proposition; more often than not predictions of success are not vindicated.

Applicants have argued essentially that: (a) a §101 rejection is improper, (b) §101 rejections equate with enablement rejections under §112-1st paragraph, and (c) since the §101 rejections is improper, it necessarily follows therefrom that an enablement rejection is improper. Applicants' argument that a §101 rejection is improper is moot: there is no §101 rejection. However, applicants' next two points are not correct. Utility rejections

and enablement rejections are not synonymous. With respect to the instant case, the compounds *per se* are not rejected as lacking enablement, nor are salts of the compounds rejected. It is only those molecular entities which are specifically identified as being "pharmaceutically acceptable" that are the target of the rejection. As indicated the term at issue ("pharmaceutically acceptable") implies therapeutic efficacy, which is not in evidence. What is sought is not a narrowing of the scope, but rather an increase in scope; specifically an increase in the scope to encompass both toxic and non-toxic salts and esters. Applicants could, if desired, add a claim which recites specific salts and esters. But recitation of "pharmaceutically acceptable" conveys an intent to use the compounds therapeutically, and the rejection will be maintained if the term at issue is retained.

*

Several of the amended claims (e.g., claims 1, 40, 45, 59, 60) contain underlining or brackets that are apparently intended to appear in the printed patent or are properly part of the claimed material. The brackets or underlining as used by the applicant are not intended to indicate amendments or changes in the claims as provided in 37 CFR 1.121(a)(2)(ii). Since underlining and brackets are normally used to indicate insertions and deletions, it is confusing to use the same in instances where the applicant desires to have the underlining and brackets appear in the published patent. If underlining or brackets are intended to appear as part of the printed patent claim, such claim should be presented in unamended form as a new claim, i.e., without the designation (amended), (twice amended), etc. as required by 37

CFR 1.121(a)(1)(B).

*

Claims 1-28, 30-35, 37-66, 73, 74, 76, 77, 79, 80, 82, 85-88, 96, 100-102 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the term "Het" is undefined.

In claim 76, at the top of the table, the designation "Tab.5" occurs. However, while a period can and should be present at the end of the claim, and may be present as a decimal point in a number, its use otherwise is considered extraneous and should be eliminated.

Claim 59 is drawn to a mixture of compounds, whereas claim 45, on which it depends is drawn to a single compound. A single compound is not a mixture. Accordingly, the claim dependence is not proper. One option would be to add a claim such as the following, and then to make claim 59 dependent on it:

> *A mixture consisting of a compound according to claim 45, together with at least one stereoisomer thereof.*

Also in claim 59, the term "racemic mixture of diasteriomers" is somewhat superfluous under the circumstances. Reference to just diasteriomers would appear sufficient.

*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600